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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/825,219	04/16/2004	Alfons Bosman	2551-149	7081

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EXAMINER	
BOESEN, AGNIESZKA	

ART UNIT	PAPER NUMBER
1648	

DATE MAILED: 08/14/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/825,219	BOSMAN ET AL.	
	Examiner	Art Unit	
	Agnieszka Boesen	1648	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *19 June 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *12-23* is/are pending in the application.

4a) Of the above claim(s) *21* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *12-20,22 and 23* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *2/24/05 and 8/25/04*
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

This Non-Final Office Action is responsive to the communication received June 19, 2006.

Election/Restrictions

Applicant's election without traverse of group I, claims 12-20, 22, and 23 is acknowledged.

Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement with respect to any other groups, the election has been treated as an election without traverse (MPEP § 818.03(a)).

Claim 21 is withdrawn because it is drawn to a non-elected invention. Claims 12-20, 22, and 23 are under examination.

Information Disclosure Statement

The Information Disclosure Statements received February 24, 2005 and August 25, 2004 have been considered and the copies are attached to this Office Action.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 17-19 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not

described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Claims are drawn to the isolated HCV envelope protein for use as medicament and a vaccine composition comprising the isolated HCV envelope protein.

A vaccine composition or a medicament can be interpreted to be a drug; a drug by definition is an agent intentioned for the use in the diagnostics, mitigation, treatment, cure, or prevention of disease in humans or in other animals. Pharmaceutical therapies in the absence of *in vivo* clinical data are unpredictable. The specification does not set forth sufficient teachings to allow one skilled in the art to use the claimed vaccine composition to treat the HCV infection. The specification does not provide teachings to establish effective dosages or methods of administration of the HCV envelope protein to treat the HCV infection. The specification provides no description and exemplification of how to use the pharmaceutical composition, without undue experimentation, for the prevention, diagnosis, alleviation, treatment, or cure of a disease in the animal to which the substance is administered. No working examples are provided which would provide sufficient guidance to allow one skilled in the art to practice the above embodiments of the invention with a reasonable expectation of success. Challenge experiments in an acceptable animal model are evidence of the ability of the HCV envelope protein immunization to protect against HCV disease. For the above reasons, it appears that undue experimentation would be required to practice the claimed invention with a reasonable expectation of success.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 12-17, 20, 22, and 23 rejected under 35 U.S.C. 102(b) as being anticipated by Grakoui et al. (Journal of Virology, 1993).

Claims are drawn to an isolated HCV envelope protein or part thereof comprising at least one Cys amino acid that is irreversibly protected and wherein the reversible protection of Cys amino acids is removed. The isolated envelope protein is chosen from the group consisting of E1s and E1p. Claims are also drawn to the isolated HCV envelope protein for use as a medicament, and for raising antibodies against HCV envelope protein. Claims are also drawn to isolated HCV protein obtained by a particular purification procedure.

Grakoui et al., disclose an isolated HCV envelope protein and particularly E1 protein comprising E1s and E1p (see the entire document).

Regarding claims 17 and 20, it is noted that the intended use of the isolated HCV envelope protein as a medicament and for raising antibodies is not limiting, because it confers no further substance to the claim and thus it is given little patentable weight (see *In re Pearson*, 494 F.2nd 1399, 1403, 181 USPQ 641, 664 (CCPA 1974)).

With regard to claims 22 and 23, which are product by process claims, the product disclosed by the prior art is identical to the claimed product, (even though it is made by a somewhat different process/the prior art is silent on the method of making). There is no evidence to show that the claimed process imparts any patentable distinction between the claimed product and that of the prior art.

M.P.E.P. Section 2113 states that: "[E]ven though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production.

If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process." *In re Thorpe*, 777 F.2d 695, 698, 227 USPQ 964, 966 (Fed. Cir. 1985).

Thus, by this disclosure Grakoui et al., anticipate the current claims.

Claims 12-20, 22, and 23 are rejected under 35 U.S.C. 102(e) as being anticipated by Watanabe et al., (US Patent 5,610,009).

Claims are drawn to an isolated HCV envelope protein or part thereof comprising at least one Cys amino acid that is irreversibly protected and wherein the reversible protection of Cys amino acids is removed. The isolated envelope protein is chosen from the group consisting of E1s and E1p. Claims are also drawn to the isolated HCV envelope protein for use as a medicament, and for raising antibodies against HCV envelope protein. Claims are also drawn to isolated HCV protein obtained by a particular purification procedure. Claims are also drawn to a vaccine composition comprising isolated HCV envelope protein.

Watanabe et al., disclose an isolated HCV envelope protein and particularly E1 protein comprising E1s and E1p (see the entire document, particularly column 3 and 5). Watanabe et al., disclose the use of isolated HCV envelope protein in vaccine composition (see column 4 lines 55-65).

Regarding claims 17 and 20, it is noted that the intended use of the isolated HCV envelope protein as a medicament and for raising antibodies is not limiting, because it confers no further substance to the claim and thus it is given little patentable weight (see In re Pearson, 494 F.2nd 1399, 1403, 181 USPQ 641, 664 (CCPA 1974)).

With regard to claims 22 and 23, which are product by process claims, the product disclosed by the prior art is identical to the claimed product, (even though it is made by a somewhat different process/the prior art is silent on the method of making). There is no evidence to show that the claimed process imparts any patentable distinction between the claimed product and that of the prior art.

M.P.E.P. Section 2113 states that: "[E]ven though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production.

If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process." *In re Thorpe*, 777 F.2d 695, 698, 227 USPQ 964, 966 (Fed. Cir. 1985).

Thus, by this disclosure Watanabe et al., anticipate the current claims.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Agnieszka Boesen whose telephone number is 571-272-8035. The examiner can normally be reached on 9:00 AM to 5:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Bruce Campell can be reached on 571-272-0974. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

AB

Agnieszka Boesen, Ph.D.
Examiner

8/11/06

Stacy B. Chen

STACY B. CHEN
PRIMARY EXAMINER